Chapter III 510(k) Summary

APR - 3 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: K082846

1. Applicant Device Information

Device Common Name: SpO2 Pulse Oximeter sensor
Device Trade/Proprietary Name:

a. APK SpO2 Pulse Oximeter Sensor (Reusable)
b. APK SpO2 Pulse Oximeter Sensor (Disposable)

Classification Information:

(1) **Classification Name:** Oximeter
(2) **Regulation Number:**870.2700
(3) **Product Code:** DQA
(4) **Class:** II
(5) **Review Panel:** Anesthesiology

2. Submitter Information

Manufacturer Name and Address
APK Technology Co., Ltd
6C, C2 Building, Industru of HengFeng Hezhou,
Xixiang, Baoan District
Shenzhen, Guangdong, 518126,China
Contact Person of the Submission
Ms. Diana Hong
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No.19, Lane 999, Zhong Shan Nan Er Road
Shanghai, China, 20030

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3. Predicate Device

Epic SpO2 Sensor-Model#E412-20(K002223)
Manufactured by:
Epic Medical Equipment Services,Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

4. Device Description

4.1 The basic technology principle

The applicant sensor APK SpO2 Pulse Oximeter Sensor (Reusable and Disposable) measure, non-invasively, the arterial oxygen saturation of blood. The measurement method is based on the red and infrared light absorption of hemoglobin and oxyhemoglobin. Light of a red and infrared light source is emitted through human tissue and received by a photodiode.

The measurement is based on the absorption of light, which is emitted through human tissue (for example through the index finger). The light comes from two sources (red LED and infrared LED) with different wavelengths and is received by a photodiode. Out of the different absorption behavior of the red and infrared light a so-called ratio can be calculated. The saturation value is defined by the percentage ratio of the oxygenated hemoglobin [HbO2] to the total amount of hemoglobin [Hb].

$SpO2 = [HbO2]/([Hb+[HbO2]]$

Those sensors contain a red and infrared light source and a photodiode receiving the non-absorbed red and infrared light. The received signals are forwarded to a measurement device that amplifies the acquired signal and an algorithm that calculates the ratio and converts via a validated calibration table the ratio to a saturation value.

The device is not software-driven.

The applicant sensors are not for implant. Those sensors are not sterile and do not need sterilization or re-sterilization. The device is for prescription. The device does contain drug or biological product.

4.2 The description of Reusable series SpO2 sensor

The Reusable series SpO2 sensor include 65 kinds of models. The mainly difference of each model SpO2 sensor included in Reusable Series SpO2 Sensors is the appearance , intended lay user and matched oximeter equipment.

We can understand that surface difference as the configuration difference, which of the Reusable series SpO2 sensor can separate into three parts as **finger clip type, soft type** and **wrapping type**. Althought the sensor have difference in surface and configuration, but all of models in the Reusable series SpO2 sensor have the same technology principle and raw material.

The Reusable series SpO2 sensor have two kinds of intended population, adult and pediatric.

The Reusable series SpO2 sensor have several kinds of matched oximeter equipment, for match those equipment, Reusable series SpO2 sensor have completed the performance test with intended oximeter.

4.3 The description of Disposable series SpO2 sensor

The Disposable series SpO2 sensor include 2 kinds of models. The mainly difference of each model SpO2 sensor included in Disposable Series SpO2 Sensors is the appearance , intended lay user and matched oximeter equipment.

The Disposable series SpO2 sensor have two kinds of intended population, adult and pediatric.

The Disposable series SpO2 sensor have several kinds of matched oximeter equipment, for match those equipment, Disposable series SpO2 sensor have completed the performance test with intended oximeter.

4.4 Test Description

The Reusable and Singe Use series SpO2 sensor are electrically operated and the electrical safety and electromagnetic compatibility following IEC 60601-1 and IEC60601-1-2.

All the information about the device performance were provided.

The Clinical Test Report following ISO 9919:2005, Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter

equipment for medical use.

5. Intended Use

5.1 the Intended Use of APK SpO2 Pulse Oximeter sensor (Reusable)

The APK SpO2 Pulse Oximeter Sensor (Resuable) is intended for spot checking or continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with oximeter equipment, which are intended for adult or pediatric patients (more than 5kg) in hospitals, hospital-type facilities, and home environments.

5.2 the Intended Use of APK SpO2 Pulse Oximeter Sensor (Disposable)

The APK SpO2 Pulse Oximeter Sensor (Disposable) is intended for Disposable when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are adults or pediatric patients (more than 5kg) in hospitals, hospital-type facilities, and home environments.

6. Substantially Equivalence Determination

Comparison Analysis
The Reusable and Disposable SpO2 sensor have same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only difference is Operating temperature, PR Measuring range, Atmosphere pressure.

Conclusion
The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2009

APK Technology Company, Limited
C/o Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Company, Limited
Suite 8D, Zhongxin Zhongshan Mansion
Number 19, Lane 999, Zhong Shan Nan Er Road
Shanghai, CHINA 20030

Re: K082846
Trade/Device Name: APK Sp02 Pulse Oximeter Sensor (Reusable)
APK Sp02 Pulse Oximeter Sensor (Disposable)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 19, 2009
Received: March 23, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud MD.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): _____

Device Name: APK SpO2 Pulse Oximeter sensor (Reusable)

Indications for Use:

The APK SpO2 Pulse Oximeter sensor (Reusable) is intended for spot checking or continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with oximeter equipment, which are intended for adult or pediatric patients (more than 5kg) in hospitals, hospital-type facilities, and home environments.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082846

Indication For Use

510(k) Number (if known): _____

Device Name: APK SpO2 Pulse Oximeter sensor (Disposable)

Indications for Use:

The APK SpO2 Pulse Oximeter sensor (Disposable) is intended for single use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are adults or pediatric patients (more than 5kg) in hospitals, hospital-type facilities, and home environments.

Prescription Use ___√___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number: K082846